



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,511	11/14/2003	William W. Alston	0175.00	9835

21968 7590 02/21/2007  
NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER
----------

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
----------	--------------

3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/714,511	<b>Applicant(s)</b> ALSTON ET.AL.	
	<b>Examiner</b> Teena Mitchell	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/2/07</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**Claims 1-9,15-20, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Valentini et.al. (4,069,819).**

With respect to claim 1, Valentini discloses a body defining a chamber ((B) having an air inlet (H) and an outlet (A), wherein the chamber is sized to receive a receptacle (C) containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber (Figs. 5, 6) and wherein the air inlet is oriented to cause air to swirl within the chamber (note Figs. 5 and 6 the inlets cause the air to swirl within the chamber note the arrows depicting air movement within the chamber); wherein the chamber comprises a longitudinal axis which is substantially parallel to an inhalation direction and wherein the chamber has a cross-section orthogonal to its longitudinal axis that is non-circular (Col. 1, lines 27-35; based on the disclosure of elements of inclined surfaces, helicoidal parts or the like it is inherent that the chamber could have a cross-section orthogonal to its longitudinal axis that is non-circular, whereby when a user inhales, air enters into the chamber through the inlet (H) to cause the receptacle to move within the chamber so that the pharmaceutical formulation exits

Art Unit: 3771

through an opening in the receptacle and is aerosolized for delivery to the user through the outlet.

With respect to claim 2, Valentini discloses wherein the receptacle (C) is a capsule.

With respect to claim 3, Valentini discloses wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45 degrees during use (Figs. 5, 6).

With respect to claim 4, Valentini discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (Fig. 5).

With respect to claim 5, Valentini discloses wherein the width of the chamber is less than the length of the capsule (Fig. 5).

With respect to claim 6, Valentini discloses a puncturing member (D) moveable within the chamber to create the opening in the receptacle.

With respect to claim 7, Valentini discloses wherein the puncture member comprises a sharpened tip for penetrating the wall of the receptacle (Figs. 3, 5).

With respect to claim 8, Valentini discloses wherein the puncture member comprises a pair of sharpened tips for penetrating the wall of the receptacle (Figs. 3, 5).

With respect to claim 9, Valentini discloses wherein the puncture member is positioned to pierce only one end of the receptacle (Figs. 3, 5).

With respect to claim 15 note rejection of claim 1 above.

With respect to claim 16, Valentini discloses wherein the receptacle is a capsule (Figs. 3, 5, 6).

Art Unit: 3771

With respect to claim 17, Valentini discloses wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45° during use (Figs. 3, 5).

With respect to claim 18, Valentini discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (Figs. 3, 5).

With respect to claim 19, Valentini discloses wherein the width of the chamber is less than the length of the capsule (Figs. 3, 5).

With respect to claim 20, Valentini discloses a puncturing member (D) moveable within the chamber to create the opening in the receptacle (Figs. 3, 5).

With respect to claims 22-24, note rejections of claims 1, 16, 20, and 21 above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

**4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

**This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).**

**Claims 11-14 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini (4,069,819).**

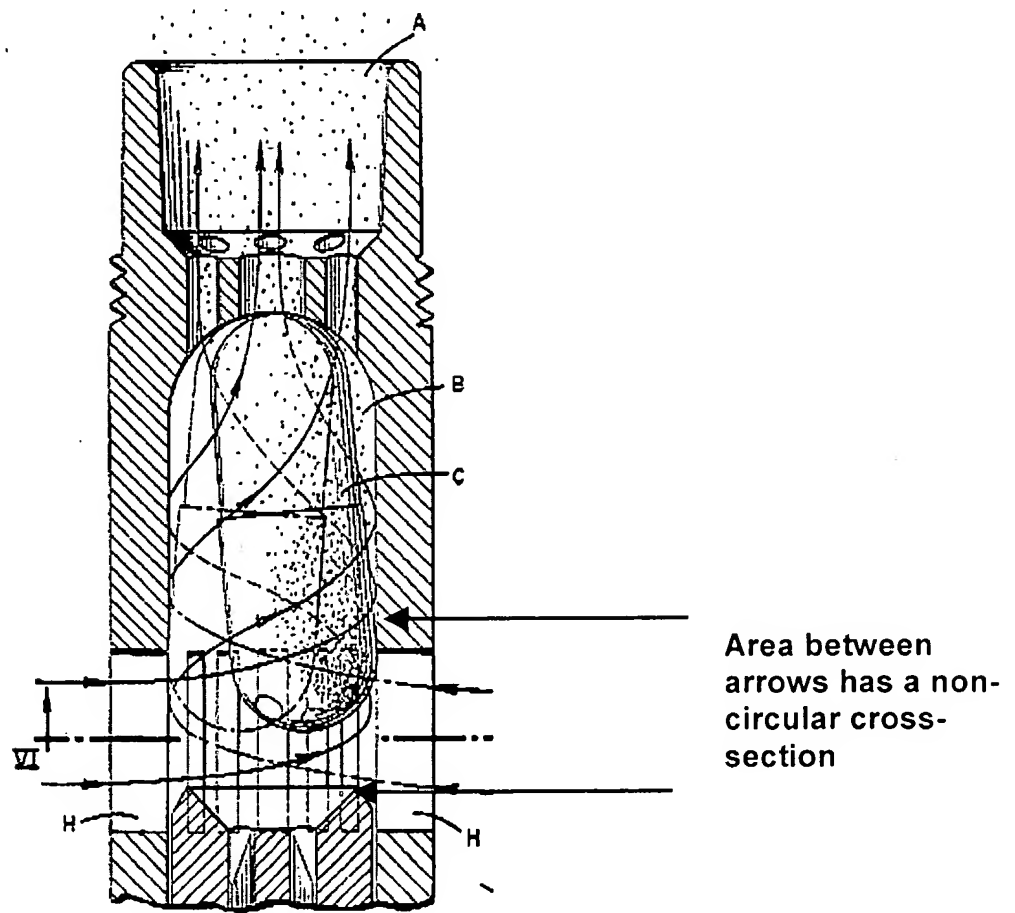
Valentini does not disclose the non-circular cross-section comprising one or more projections that extend into the chamber. Applicant has not disclosed that having one or more projections is better than any other means for deagglomeration of particles in an inhaler device. Accordingly, the use of one or more projections is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Valentini.

With respect to claims 12-14, note rejection of claim 11 above.

With respect to claims 26-28 the method steps would have been obvious because they would have resulted from the use of the device of Valentini.

### ***Response to Arguments***

Applicant's arguments filed 8/10/05 have been fully considered but they are not persuasive. The applicant argues that Valentini does not have a cross-section orthogonal to its longitudinal axis that is non-circular (note illustration of Fig. 5 below). As for Valentini not being readable upon the air inlet oriented to cause air to swirl within the chamber, applicant is directed to Fig. 6 of Valentini it is clear from the arrows depicted that air is swirling in the chamber and therefore readable upon the newly added claim limitations.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

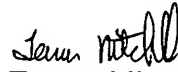
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Teena Mitchell  
Primary Examiner  
Art Unit 3771  
February 20, 2007

  
TKM